JAN 1 8 2002

K014184

510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

Submitter's Name: Guidant Corporation

Submitter's Address: 3200 Lakeside Drive
Santa Clara, CA 95052

Telephone: 408/845-1067
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Contact Person: Saba Modjarrad

Date Prepared: December 17, 2001

Device Trade Name: DYNALINK™ .035 Biliary Self-Expanding Stent System

Device Common Name: Biliary Stent

Device Classification Name: Biliary Catheter

Device Classification: Class II

Summary of Substantial Equivalence:

The design, materials, method of delivery and intended use features of DYNALINK™ .035 Biliary Self-Expanding Stent System are substantially equivalent with regard to these features in the predicate device, the DYNALINK™ .035 Biliary Self-Expanding Stent System (K011881, July 18, 2001).

Device Description:

The DYNALINK™ .035 Biliary Self-Expanding Stent System is a catheter designed to deploy a self-expanding nickel titanium (Nitinol) stent into the biliary tree.

The catheter body is constructed from two coaxial members. The inner member (IM) is compatible with a .035" guide wire in an over-the-wire configuration. The outer member (OM) is composed of a distal sheath that constrains the unexpanded stent, an outer shaft over most of the catheter length, and a proximal handle used to retract the assembly.

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Intended Use:

The DYNALINK™ .035 Biliary Self-Expanding Stent System is indicated for palliation of malignant strictures in the biliary tree.

Technological Characteristics:

Comparisons of the new and predicate devices show that technological characteristics such as materials, biocompatibility, performance properties, sterilization and packaging are substantially equivalent to the currently marketed predicate devices. The design modification of the new biliary stent system compared to that of the predicate biliary stent system is the length of the stent.

Performance Data:

The safety and effectiveness of the DYNALINK™ .035 Biliary Self-Expanding Stent System has been demonstrated through data collected from *in vitro* bench tests and analyses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 8 2002

Ms. Saba Modjarrad
Regulatory Associate II
Guidant Corporation
3200 Lakeside Drive
SANTA CLARA, CA 95054-2807

Re: K014184
Trade/Device Name: DYNALINK™ .035 Biliary Self-Expanding Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: December 17, 2001
Received: December 20, 2001

Dear Ms. Modjarrad:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K014184

Device Name: DYNALINK™ .035 Biliary Self-Expanding Stent System

FDA's Statement of the Indications For Use for device:

The DYNALINK™ .035 Biliary Self-Expanding Stent System is indicated for the palliation of malignant strictures in the biliary tree.

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K014184